

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stephen R. Hanson  
Serial No: Not yet assigned  
Conf. No: Not yet assigned  
Filed: Herewith  
For: METHODS AND COMPOSITIONS FOR TREATING PLATELET-RELATED DISORDERS  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

**Mail Stop Patent Application**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing of the application and before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application:

International Search Report for PCT/US00/25781, filed September 21, 2000 (copy enclosed)

The Applicant would like to bring to the Examiner's attention the following co-pending application (copy enclosed):

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>
E00355.70006.US	TBD	June 24, 2003

PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

PART IV: Remarks

Documents cited on the attached form PTO-1449 (modified) are enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

Serial No.: Not yet assigned

- 3 -

Art Unit: Not yet assigned

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:



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Docket No. H00646.70001.US

Dated: June 25, 2003

x6/31/03x

FORM PTO-1449/A and B (Modified)		APPLICATION NO.: Not yet assigned		ATTY. DOCKET NO.: H00646.70001.US	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		FILING DATE: June 25, 2003			
		APPLICANT: Stephen R. Hanson			
		GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned	
Sheet	1	of	4		

#### U.S. PATENT DOCUMENTS

Examiner's Initials#	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*A1	3,932,407		Beverung, Jr., et al.	01/13/76
	*A2	3,978,213		Lapinet, et al.	08/31/76
	*A3	4,088,753		Parmer	05/09/78
	*A4	4,146,718		Jenks, et al.	03/27/79
	*A5	4,206,214		Harker, et al.	06/03/80
	*A6	4,208,521		Crenshaw, et al.	06/17/80
	*A7	4,357,330		Fleming, Jr., et al.	02/02/82
	*A8	4,393,063		Moncada	07/12/83
	*A9	4,404,212		Moncada	09/13/83
	*A10	4,406,904		Welle, et al.	09/27/83
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	*A19	5,391,557		Cullinan, et al.	02/21/95
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	*A30	6,156,753		Doherty, Jr., et al.	12/05/00
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	A33	6,376,242		Hanson	04/23/02

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials#	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	*B1	EP	0 260 527	A		03/23/88	Abstract
	*B2	EP	0 778 258			06/97	
	*B3	EP	0 994 114			04/00	

	*B4	EP	0 514 917			11/25/92	
	*B5	EP	0 904 783			03/99	
	*B6	HU	206 496	B		11/30/92	Abstract
	*B7	PCT	WO99/08524			02/99	
	*B8	PCT	WO99/08525			02/99	
	*B9	PCT	WO99/20223			04/99	
	*B10	PCT	WO93/23426			25/11/93	Abstract
	*B11	PCT	WO99/34792			07/15/99	
	*B12	UK	GB2,256,195			12/92	

# OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials#	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*C1	Al-Jibouri, L.M. and Najim, R.A., "Effect of dipyridamole on blood glucose and liver cyclic AMP levels and platelet count during endotoxaemia in mice", <i>Clin. Exp. Pharmacol. Physiol.</i> , 15(7):527-32 (1988) <b>ABSTRACT</b>	
	*C2	Andes, et al., "Inhibition of platelet production induced by an antiplatelet drug, anagrelide, in normal volunteers", <i>Thromb Haemost.</i> , 52(3):325-8 (1984)	
	*C3	Balan, K.K and Critchley, M., "Outcome of 259 patients with primary proliferative polycythaemia (PPP) and idiopathic thrombocythaemia (IT) treated in a regional nuclear medicine department with phosphorus-32—a 15 year review", <i>Br. J. Radiol.</i> , 70(839):1169-73 (1997) <b>ABSTRACT</b>	
	*C4	Balduini, et al., "Effect of anagrelide on platelet count and function in patients with thrombocytosis and myeloproliferative disorders", <i>Haematologica</i> , 77(1):40-3 (1992) <b>ABSTRACT</b>	
	*C5	Barnathan, et al., "Aspirin and dipyridamole in the prevention of acute coronary thrombosis complicating coronary angioplasty", <i>Circulation</i> , 76(1):125-134 (1987)	
	*C6	Bellucci, et al., "Positive and negative regulation of megakaryocytopoiesis", <i>C.R. Seances Soc. Biol. Fil.</i> , 190(5-6):515-32 (1996) <b>ABSTRACT</b>	
	*C7	Bunn, H.F., "Pathophysiology of the anemias", <i>Harrison's Principles of Internal Medicine: Hematology and Oncology</i> , 1514, 1566-67 New York, McGraw-Hill, (1991)	
	*C8	Cazenave, J.P. and Gachet, C., "Anti-platelet drugs: do they affect megakaryocytes?", <i>Baillieres Clin Haematol</i> , 10(1):163-80 (1997)	
	*C9	Chen, et al., "Thrombospondin, a negative modulator of megakaryocytopoiesis", <i>J. Lab. Clin. Med.</i> , 129(2):231-8 (1997) <b>ABSTRACT</b>	
	*C10	Cortelazzo, et al., "Hydroxyurea for patients with essential thrombocythemia and a high risk of thrombosis", <i>N. Engl. J. Med.</i> , 332(17):1132-6 (1995) <b>ABSTRACT</b>	
	*C11	Dale, et al., "Chronic thrombocytopenia is induced in dogs by development of cross-reacting antibodies to the MpL ligand", <i>Blood</i> , 90(9):3456-3461 (1997)	
	*C12	Davies, et al., "Adverse events reported by postmenopausal women in controlled trials with raloxifene", <i>Obstetrics &amp; Gynecology</i> , 93(4):558-565 (1999)	
	*C13	De Serres, et al., "Immunogenicity of thrombopoietin mimetic peptide GW395058 in BALB/c mice and New Zealand white rabbits:evaluation of the potential for thrombopoietin neutralizing antibody production in man", <i>Stem Cells</i> , 17:203-209 (1999)	
	*C14	Deng, et al., "A monoclonal antibody cross-reactive with human platelets, megakaryocytes, and common acute lymphocytic leukemia cells", <i>Blood</i> , 61(4):759-764 (1983)	
	*C15	Gaver, et al., "Disposition of anagrelide, an inhibitor of platelet agregation", <i>Clin. Pharmacol. Ther.</i> , 29(3):381-6 (1981) <b>ABSTRACT</b>	
	*C16	Gewirtz, et al., "Cell-mediated suppression of megakaryocytopoiesis in acquired amegakaryocytic thrombocytopenic purpura", <i>Blood</i> , 68(3):619-26 (1986) <b>ABSTRACT</b>	
	*C17	Glushkov, et al., "Changes in hemostatic system indices during hemosorption in healthy dogs", <i>Biull Eksp Biol. Med.</i> , 94(7):95-8 (1982) <b>ABSTRACT</b>	
	*C18	Goldberg, et al., "Thrombocytotic suppression of megakaryocyte production from stem cells", <i>Blood</i> , 49(1):59-69 (1977) <b>ABSTRACT</b>	
	*C19	Gugliotta, et al., "In vivo and in vitro inhibitory effect of alpha-interferon on megakaryocyte colony growth in essential thrombocythaemia", <i>Br. J. Haematol.</i> , 71(2):177-81 (1989) <b>ABSTRACT</b>	
	*C20	Herron, et al., "Inhibition of megakaryocytic colonies <i>in vitro</i> by anagrelide", <i>Clin. Res.</i> , 34(2):459A (1986) <b>ABSTRACT</b>	
	*C21	Hung, et al., "Focused antithrombotic therapy: novel anti-platelet salicylates with reduced	

		ulcerogenic potential and higher first-pass detoxification than aspirin in rats", <i>J. Lab. Clin. Med.</i> , 132(6):469-77 (1998) <b>ABSTRACT</b>		
	*C22	Jones, et al., "Inhibitors of cyclic AMP phosphodiesterase. 1. Analogues of cilostamide and anagrelide", <i>J. Med. Chem.</i> , 30(2):295-303 (1987) <b>ABSTRACT</b>		
	*C23	Lecomte-Raclet, et al., "New insights into the negative regulation of hematopoiesis by chemokine platelet factor 4 and related peptides", <i>Blood</i> , 91(8):2772-80 (1998) <b>ABSTRACT</b>		
	*C24	Ludwig, et al., "Interferon-alfa corrects thrombocytosis in patients with myeloproliferative disorders", <i>Cancer Immunol. Immunother.</i> , 25(3):266-73 (1987) <b>ABSTRACT</b>		
	*C25	Mazur, et al., "Analysis of the mechanism of anagrelide -induced thrombocytopenia in humans", <i>Blood</i> , 79(8):1931-1937 (1992)		
	*C26	Mazzuconi, et al., "Pipobroman therapy of essential thrombocythemia", <i>Scand J. Haematol.</i> , 37(4):306-9 (1986) <b>ABSTRACT</b>		
	*C27	Mazzuconi, et al., "Therapy with Anagrelide in patients affected by essential thrombocythemia: preliminary results", <i>Haematologica</i> , 77(4):315-7 (1992) <b>ABSTRACT</b>		
	*C28	McCune, et al., "Precipitous fall in platelet count with anagrelide: case report and critique of dosing recommendations", <i>Pharmacotherapy</i> , 17(4):822-6 (1997) <b>ABSTRACT</b>		
	*C29	Meanwell, et al., "Inhibitors of blood platelet cAMP phosphodiesterase. 2. Structure-activity relationships associated with 1,3-dihydro-2H-imidazo[4,5-b]quinolin-2-ones substituted with functionalized side chains", <i>J. Med. Chem.</i> , 35(14):2672-87 (1992) <b>ABSTRACT</b>		
	*C30	Nagae, S. and Hori, Y., "Immune thrombocytopenia due to Tranilast (Rizaben): detection of drug-dependent platelet-associated IgG", <i>J. Dermatol.</i> , 25(11):706-9 (1998)		
	*C31	Negrev, et al., "Influence of nonselective beta-adrenergic impacts on the effects of thrombopoietin in mice", <i>Acta Physiologica et Pharmacologica Bulgaria</i> , 13:1:35-39 (1987)		
	*C32	Ramires, et al., "Effect of ticlopidine and dipyridamole on platelet aggregation and count in patients with chronic stable angina pectoris", <i>Arq Bras. Cardiol.</i> , 56(4):323-7 (1991) <b>ABSTRACT</b>		
	*C33	Robak, T, et al., "Anagrelide—new antiplatelet drug", <i>Acta Haematol Pol.</i> , 25(4):309-15 (1994) <b>ABSTRACT</b>		
	*C34	Sato, et al., "Multivariate analysis of risk factors for thrombus formation in University of Tokyo ventricular assist device", <i>J. Thorac. Cardiovasc. Surg.</i> , 106:520-7 (1993)		
	*C35	Scott, et al., "Local delivery of an antithrombin inhibits platelet-dependent thrombosis", <i>Circulation</i> , 90(4):1951-1955 (1994)		
	*C36	Seiler, et al., "Effects of anagrelide on platelet cAMP levels, cAMP-dependent protein kinase and thrombin-induced Ca++ fluxes", <i>J. Pharmacol Exp. Ther.</i> , 243(2):767-74 (1987) <b>ABSTRACT</b>		
	*C37	Shinagawa, et al., "Allopurinol induced pancytopenia in a patient with myeloproliferative disorder", <i>Rinsho Ketsueki</i> , 38(1):64-71 (1997) <b>ABSTRACT</b>		
	*C38	Smith, J.B. "Effect of thromboxane synthetase inhibitors on platelet function: enhancement by inhibition of phosphodiesterase", <i>Thromb Res.</i> , 15:28(4):477-85 (1982) <b>ABSTRACT</b>		
	*C39	Solberg, et al., "The effects of anagrelide on human megakaryocytopoiesis", <i>Br. J. Haematol.</i> , 99(1):174-80 (1997) <b>ABSTRACT</b>		
	*C40	Thaulow, et al., "Blood platelet count and function are related to total and cardiovascular death in apparently healthy men", <i>Circulation</i> 84(2):613-617 (1991)		
	*C41	Trowbridge, et al., "Platelet production in myocardial infarction and sudden cardiac death", <i>Thromb. Haemost.</i> , 52(2):167-171 (1984)		
	*C42	Van de Pette, "Primary thrombocythaemia treated with busulphan", <i>Br. J. Haematol.</i> , 62(2):229-37 (1986) <b>ABSTRACT</b>		
	*C43	van der Loo, et al., "Megakaryocytes and platelets in vascular disease", <i>Bailliere's Clinical Haematology</i> , 10(1):109-123 (1997)		
	*C44	Venuti, et al., "Inhibitors of cyclic AMP phosphodiesterase. 3. Synthesis and biological evaluation of pyrido and imidazolyl analogues of 1,2,3,5-tetrahydro-2-oxoimidazole[2,1-b]quinazoline", <i>J. Med. Chem.</i> , 31(11):2136-45 (1988) <b>ABSTRACT</b>		
	*C45	Wada, et al., "Characterization of the truncated thrombopoietin variants", <i>Biochem. Biophys. Res. Comm.</i> , 213(3):1091-1098 (1995)		
	*C46	Wadenvik, et al., "The effect of alpha-interferon on bone marrow megakaryocytes and platelet production rate in essential thrombocythemia", <i>Blood</i> , 77(10):2103-8 (1991) <b>ABSTRACT</b>		
	*C47	Wilhelmsen, L., "Thrombocytes and coronary heart disease", <i>Circulation</i> 84(2):936-938 (1991)		
	*C48	Yataganas, et al., "alpha Interferon treatment of essential thrombocythaemia and other myeloproliferative disorders with excessive thrombocytosis", <i>Eur. J. Cancer</i> , 27 Suppl 4:S69-71 (1991) <b>ABSTRACT</b>		
	*C49	Yeager, et al., "Effects of cyclophosphamide on murine bone marrow and splenic megakaryocyte-CFC, granulocyte-macrophage-CFC, and peripheral blood cell levels", <i>J. Cell.</i>		

		<i>Physiol.</i> , 112(2):222-8 (1982) <b>ABSTRACT</b>		
	*C50	Harker, et al., "Regulation of Platelet Production and Function by Megakaryocyte Growth and Development Factor in Nonhuman Primates", <i>Blood</i> , Vol. 87, No. 5, pp. 1833-1844, (1996)		
	*C51	Harker, "Platelets in Thrombotic Disorders: Quantitative and Qualitative Platelet Disorders Predisposing to Arterial Thrombosis", <i>Seminars in Hematology</i> , Vol. 35, No. 3, pp. 241-252, (1998)		
	*C52	van der Loo, et al. "A Role for Changes in Platelet Production in the Cause of Acute Coronary Syndromes", <i>Arterioscler Thromb Vasc Biol.</i> , Vol. 19, pp. 672-679 (1999)		
	*C53	Broudy, et al., "Thrombopoietin Stimulates Colony-Forming Unit-Megakaryocyte Proliferation and Megakaryocyte Maturation Independently of Cytokines that Signal through the gp130 Receptor Subunit," <i>Blood</i> , Vol. 8, No. 6, pp. 2026-2032 (1996)		
	*C54	Luoh, et al., "Role of the Distal Half of the CMPL Intracellular Domain or Control of Platelet Production by Thrombopoietin in Vivo," <i>Mol. Cell. Biol.</i> , Vol. 20, No. 2, pp. 507-515 (2000)		
	*C55	Landolfi, et al., "Aspirin in Polycythemia Vera and Essential Thrombocythemia: Current facts and Perspectives", <i>Leukemia and Lymphoma</i> , 1996, Vol. 22, Suppl. 1, pp. 83-86		
	*C56	Lane, et al., "Anagrelide metabolite induces thrombocytopenia in mice by inhibiting megakaryocyte maturation without inducing platelet aggregation," <i>Experimental Hematology</i> , 2001, Vol. 29, pp. 1417-1424		
	*C57	Harker, "Platelets in Thrombotic Disorders: Quantitative and Qualitative Platelet Disorders Predisposing to Arterial Thrombosis", <i>Seminars in Hematology</i> , Vol. 35, No. 3, pp. 241-252 (1998)		
	*C58	van der Loo, et al., "A Role for Changes in Platelet Production in the Cause of Acute Coronary Syndromes", <i>Arterioscler Thromb Vasc Biol.</i> , Vol. 19, pp. 672-679 (1999)		
	*C60	Hennekens, "Update on aspirin in the treatment and prevention of cardiovascular disease" <i>Am. Heart J.</i> , 137 (4 Pt2):S9-S13 (1999) Abstract only		
	*C61	Tang, et al. "Inhibition of platelet function by antithrombotic agents which selectively inhibit low-Km cyclic 3',5'-adenosine monophosphate phosphodiesterase", <i>J. Lab.Clin. Med.</i> , 95(2):241-57 (1980)		
	*C62	Fleming, et al., "A Potent New Inhibitor of Platelet Aggregation and Experimental Thrombosis, Anagrelide (BL-4162A)", <i>Throm. Res.</i> , 15(3-4):373-88 (1979)		
	*C63	Merck Research Laboratories, N. J., "the merck manual", 1999, p. 918, column 2, paragraph 4		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 09/666,223, filed September 21, 2000, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]